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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|----------------------|------------------------------------|----------------------|---------------------|------------------|--|--|
| 10/509,732 | 99,732 09/30/2004 Clare J. Watkins | | BJS-620-334 | 9948 | | |
| 23117 NIXON & VAN | 7590 09/03/200 NDERHYE, PC | EXAMINER | | | | |
| 901 NORTH G | LEBE ROAD, 11TH F | LEESER, ERICH A | | | | |
| ARLINGTON, | VA 22203 | | ART UNIT | PAPER NUMBER | | |
| | | | 1624 | | | |
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| | | | MAIL DATE | DELIVERY MODE | | |
| | | | 09/03/2008 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Commons | | 1 | Application No. Applicant(s) | | | | | | |
|--|---|-----------------------|------------------------------|---|--------------------|-------------|--|--|--|
| | | | 10/509,732 | | WATKINS ET AL. | | | | |
| Office Action Summary | | | xaminer | | Art Unit | | | | |
| | | | Erich A. Leeser | | 1624 | | | | |
| Period fo | The MAILING DATE of this commur or Reply | nication appea | rs on the cover | sheet with the c | orrespondence ad | ldress | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | | | |
| Status | | | | | | | | | |
| 1)[\ | Responsive to communication(s) file | ed on 25 lune | 2008 | | | | | | |
| • | Responsive to communication(s) filed on <u>25 June 2008</u> . This action is FINAL . 2b) This action is non-final. | | | | | | | | |
| 3) | | <i>,</i> — | | | secution as to the | e merits is | | | |
| ٥,١ | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | | |
| Dispositi | on of Claims | · | | · | | | | | |
| · · | | Ris/are nendir | na in the annlic | ation | | | | | |
| • | Claim(s) 80-84,87-116 and 119-173 is/are pending in the application. | | | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | | |
| · · · · · · · · · · · · · · · · · · · | 5) Claim(s) is/are allowed. 6) Claim(s) <u>80-84, 87-116, and 119-173</u> is/are rejected. | | | | | | | | |
| · · | Claim(s) <u>60-64, 67-776, and 719-77</u> Claim(s) is/are objected to. | <u>o</u> is/ale lejec | ieu. | | | | | | |
| | Claim(s) are subject to restrict | ction and/or e | lection require | ment | | | | | |
| 0) | Claim(3) are subject to resum | ction and/or e | iection require | ment. | | | | | |
| Applicati | on Papers | | | | | | | | |
| 9) | The specification is objected to by th | e Examiner. | | | | | | | |
| 10) | The drawing(s) filed on is/are | : а)∏ ассер | ted or b)⊡ obj | ected to by the E | xaminer. | | | | |
| | Applicant may not request that any object | ection to the dra | awing(s) be held | in abeyance. See | 37 CFR 1.85(a). | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | | |
| Priority ι | ınder 35 U.S.C. § 119 | | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | | |
| 2) Notic 3) Inform | t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (Fination Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date | PTO-948) | 5) | Interview Summary Paper No(s)/Mail Da Notice of Informal Pa Other: | te | | | | |

DETAILED ACTION

This action is in response to Applicant's Amended Claims and Remarks dated June 25, 2008, in which Applicant submitted a new specification and cancelled claims 169-173. Claims 80-84, 87-116, and 119-173 are under examination.

Claim Rejections - 35 USC § 112

Examiner previously rejected claims 80-173 because the specification does not reasonably provide enablement for making solvates of the claimed compounds. Applicant has now deleted this term from the claims. As such, Examiner withdraws this rejection.

Examiner previously rejected claims 169-173 as failing to comply with the enablement requirement because the specification does not enable the instant compounds to inhibit HDAC in a cell, treat a condition mediated by HDAC, a proliferative condition, cancer or psoriasis with a therapeutically-effective amount of a compound of claim 80 or enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Based on Applicant's cancellation of claims 169-173, this rejection is now moot.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 80-84, 87-116, and 119-173 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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i) The "amide", "ester" and "ether" forms of the claimed compounds of formula (1) are not clear. What is intended by these terms? Where in the structural formula (1) do these functional groups appear. Applicant does not clearly explain or illustrate via examples. Clarification is required.

Claim Rejections 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 80, 81, 84, 98, 101, 116, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 135, 141, 142, 145, 146, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, and 168 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Owen, et al., WO 00/56704.

Owen, et al., WO 00/56704 teaches hydroxamic acid derivatives and teaches several piperazinyl compounds having a terminal carbamic acid group. See for example the compound of Example 11 (the structural formula depicted below):

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(Q1 and J1 can be a "covalent

bond" according to the claims).

Claim 80, however, requires that Q2 "has a backbone length of at least 4 atoms". This phrase is illustrated in the specification at page 39. As per the explanation in the specification, the above reference compound has a backbone length of 3 atoms separating the SO2 and - C(O)NHOH groups. The instant claims require at least 4 atoms. This may be achieved either by extending the alkylene group (i.e., for example replacing -CH2- by -CH2-CH2-) or by changing the position of the hydroxamic acid on the phenyl ring (i.e., having -CH2- and the -C(O)NHOH groups in 1,3- or 1,4-positions). Therefore, the claimed compounds are structural analogs (homologs or isomers) of the reference compounds.

To those skilled in the chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). The instant claimed compounds would have been obvious, because one skilled in the art would have been motivated to prepare homologs of the compound taught in the reference with the expectation of obtaining compounds which could be used in carbamic acid compounds. Therefore, the instant claimed compounds would have been suggested to one skilled in the art. Further, compounds which differ only in the placement of substituents in a ring system are

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obvious variants of one another absent unexpected results. *In re Jones*, 162 F.2d 638, 74 USPQ 152 (CCPA 1947).

As such, claims 80, 81, 84, 98, 101, 116, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 135, 141, 142, 145, 146, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, and 168 are rendered obvious by Owen, et al., WO 00/56704.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624

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